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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/040,538	12/28/2001	Stephen D. Pacetti	50623.149	3811

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EXAMINER
JOLLEY, KIRSTEN

ART UNIT	PAPER NUMBER
1762	

DATE MAILED: 09/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/040,538	PACETTI ET AL.	
	Examiner	Art Unit	
	Kirsten C Jolley	1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *8,12,14 and 27-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-11,13 and 15-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/6/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I in the reply filed on July 2, 2004 is acknowledged. Claims 8 and 27-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected device and apparatus.

2. Claims 12 and 14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on July 2, 2004.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-7, 11, 13, and 17-19, and 21-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Castro et al. (US 6,395,326).

Castro et al. discloses a method of coating implantable, expandable stents with a coating composition comprising a solvent, polymer, and active agent. Castro et al. discloses that dimethylacetamide may be used as the solvent in its coating composition (col. 13, lines 1-10).

Dimethylacetamide is not considered volatile according to the invention and has a vapor pressure of less than 17.54 Torr (1.5 Torr at 20 C). Castro et al. teaches coating the stents by using a dispenser having a nozzle through which composition is delivered, which meets the limitation of spraying. Castro et al. also teaches that a heating assembly 52 is used for controlled drying of the coating (col. 11). Heating assembly 52 comprises heating nozzle 56 which directs heated air at the coated stent to induce evaporation of the solvent, as disclosed in col. 18, lines 1-12.

As to claim 5, Castro et al. discloses that the polymer in the coating solution may be ethylene vinyl alcohol copolymer (col. 12, line 63), and the solvent may be dimethylacetamide as discussed above.

As to claim 6, Castro et al. teaches use of paclitaxel or docetaxel as the active agent in the coating solution in col. 14, lines 1-2.

As to claim 7, Castro et al. teaches that multiple layers may be applied at col. 19, lines 4-8.

As to claims 17-18, the stent of Castro et al. is rotated and moved linearly along its axis during delivery of the coating solution to the device because a stent is cylindrical and longitudinal and because Castro et al. teaches that the delivery device may be stationary while the stent moves thereunder (col. 16, lines 1-11).

As to claim 19, Castro et al. teaches that the stent may be expanded during deposition (col. 7, line 53).

As to claim 22, it is noted that the temperature of the implantable device will necessarily be increased (above atmospheric temperature) at least a little bit during the heating/drying of the coating composition.

With respect to claims 3 and 23-24 which require directing gas simultaneous with applying the coating composition, it is noted that Castro et al. teaches that delivery of the composition may be applied using air pressure (col. 9, lines 28-35). Air pressure acting upon a coating solution comprising solvent necessarily induces evaporation of the solvent. Likewise, the temperature of the air used to apply air pressure will inherently be adjusted to induce evaporation of the solvent.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 9-10, 15-16, 20, and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castro et al.

Castro et al. is applied for the reasons discussed above in section 4.

As to claims 9-10, Castro et al. teaches that nozzle 26 is positioned over or in contact with strut 68 of the stent (col. 16, lines 50-51). Castro et al. is silent with regard to the exact distance above the stent, or the flow rate of coating material applied to the stent. With respect to claim 15, Castro et al. is also silent with regard to the flow rate of the heating air applied to dry the coating. These are all result-effective variables depending upon the particular coating solution used, the size and shape of the stent being coated, the desired thickness of the coating, etc. It is well settled that determination of optimum values of cause effective variables such as these process parameters is within the skill of one practicing in the art. *In re Boesch*, 205 USPQ 215 (CCPA 1980). As to claim 16, it is well known to add radiopaque elements, such as gold elements, to bioactive compositions for coating stents. It would have been obvious for one having ordinary skill in the art to have added a radiopaque element to Castro et al.'s coating compositions because Castro et al. broadly teaches that any bioactive/therapeutic agents which are currently available are equally applicable for use with its invention.

As to claim 20, Castro et al. teaches that the heating may be conducted in an anhydrous atmosphere. It would have been obvious for one having ordinary skill in the art to have used inert gas as the heating gas upon seeing this teaching because inert gases are anhydrous.

As to claim 25, Castro et al. is silent with regard to the temperature of the gas used for applying air pressure. It would have been obvious to have used a gas at room temperature (25 C) in the absence of a teaching of a particular temperature since it would be most economical and efficient to use room temperature air. It is noted that claim 26 is broad enough to read on use of a gas that is only slightly above ambient temperature. This is not a patentable variation over

using room temperature air. It is noted that air would necessarily be heated slightly during the process of being conveyed through the dispenser tubing and nozzle.

8. Claims 1-7, 9-11, 13, and 15-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding et al. (US 6,358,556) in view of You et al. (US 6,407,009).

Ding et al. discloses a method of coating implantable stents with a thin layer of a coating composition comprising a solvent, polymer, and active agent (see Abstract and col. 3, lines 29-33). Ding et al. discloses coating by spraying the composition on a rotating stent, using an evaporative solvent that has a high vapor pressure/is volatile to produce a desired viscosity and layer thickness (col. 3, lines 48-53). Ding et al. discloses using a solvent of tetrahydrofuran (THF) in its Examples; THF has a vapor pressure greater than 17.54 Torr at ambient temperature (129 Torr at 20 C). Ding et al. teaches using an air brush to apply the coating, therefore Ding et al. teaches directing a gas onto the implantable device. However, Ding et al. lacks a teaching of directing a gas on to the implantable device whereby the temperature of the gas is adjusted to inhibit the evaporation of the solvent.

It is very well known in the coating art to control the evaporation of solvent from a coating material (either to speed up evaporation or slow down evaporation) by adjusting the temperature of the atmosphere surrounding the coating. You et al. is cited as an exemplary teaching of such a concept (col. 5, line 37 to col. 6, line 6; col. 6, line 40 to col. 7, line 8; and col. 7, line 53 to col. 8, line 10). You et al. is directed to method of coating with resist liquids which comprise polymer in volatile solvent, and teaches that if solvent evaporation rates are too high then the deposited material can crack. You et al. teaches that, in order to control and slow the

rate of evaporation, the temperature inside a deposition chamber can be decreased during deposition. One means for cooling is via cold air, for example using cooled inert bias gas (col. 5, line 63 to col. 6, line 6). It would have been obvious to have incorporated the teachings of You et al. into the process of Ding et al. by performing coating in a deposition chamber which is cooled using cool air or inert gas to control the evaporation of the high vapor pressure solvent in the method of Ding et al. in order to ensure that the deposited coating does not crack due to too rapid evaporation, particularly since such a method of controlling evaporation using atmospheric temperature is well known in the coating art. One skilled in the art would have expected successful results since both references are similarly related to the deposition of polymeric coatings in a volatile solvent on a rotating substrate.

As to claim 5, Ding et al. generally discloses that "thermoplastic elastomers in general" may be used as the polymeric material in its coating compositions (col. 4, line 59). It would have been obvious to one having ordinary skill in the art to have selected a specific thermoplastic elastomer, such as ethylene vinyl alcohol copolymer, from the broad class taught by Ding et al. because a specific member of the broad class would be expected to function in a similar and successful manner of providing hydrophobic biostable elastomeric coating properties to a stent. Further it would have been obvious to have substituted one solvent for another with the expectation of equivalent results since the solvent merely evaporates from the coating after application.

As to claim 6, Ding et al. generally teaches the use of antibiotics as the biologically active species in the composition of his invention (col. 5, line 2). While Ding et al. does not specifically teach the use of actinomycin D as the bioactive agent, it is noted that actinomycin D

is an antibiotic agent well-known in the medical coating art. It would have been obvious to one having ordinary skill in the art to have selected a specific antibiotic, such as actinomycin D, from the broad class of antibiotics taught by Ding et al. because a specific member of the broad class would be expected to function in a similar and successful manner of providing antibiotic properties to a stent.

As to claim 7, Ding et al. teaches applying multiple layers by spraying at col. 11, lines 7-11.

As to claims 9-10, Ding et al. is silent with regard to the distance from the tip of the sprayer to the substrate and the flow rate of coating material. These are known result-effective variables depending upon the desired thickness, viscosity of coating material, exact type of sprayer used, etc. It is well settled that determination of optimum values of cause effective variables such as these process parameters is within the skill of one practicing in the art. *In re Boesch*, 205 USPQ 215 (CCPA 1980).

As to claim 13, it is noted that the flow of chilled air in a deposition chamber, as in the process of Ding et al. in view of You et al., would necessarily comprise air/gas which flows at an angle relative to the direction of the spray. As to claim 15, the flow rate of the chilled air/gas would be determined through routine experimentation depending upon the degree of cooling needed. As to claim 16, it is well known to add radiopaque elements, such as gold elements, to bioactive compositions for coating stents. It would have been obvious for one having ordinary skill in the art to have added a radiopaque element to Ding et al.'s coating compositions because Ding et al. is specifically not limiting as to the bioactive agents which may be used in its invention.

As to claim 22, it is noted that the temperature of the implantable device will necessarily be decreased (lower than atmospheric temperature) as well as the coating material since it is located in a chamber of chilled air/gas.

As to claim 25, the temperature of the chilled air/gas is necessarily lower than 25 C since it is "chilled."

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hossainy et al. (US 6,153,252) similarly teaches a process of coating a stent with a coating solution comprising dimethylacetamide as the solvent.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kirsten C Jolley whose telephone number is 571-272-1421. The examiner can normally be reached on Monday to Thursday and every other Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P Beck can be reached on 571-272-1415. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kirsten C Jolley
Patent Examiner
Art Unit 1762

kcj